

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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UNITED STATES OF AMERICA,	:
	Case No. 11 Civ. 8196 (CM)
Plaintiff,	:
	<b><u>NOVARTIS PHARMACEUTICALS</u></b>
v.	:
	<b><u>CORPORATION’S ANSWER TO SECOND</u></b>
NOVARTIS PHARMACEUTICALS	:
CORPORATION,	<b><u>AMENDED COMPLAINT-IN-</u></b>
	<b><u>INTERVENTION OF</u></b>
	<b><u>THE UNITED STATES</u></b>
Defendant.	:
-----X	

Defendant Novartis Pharmaceuticals Corporation (“Novartis”), for its Answer to the Second Amended Complaint-in-Intervention of the United States of America (“Complaint”), dated August 28, 2014, which was filed by the United States of America, by its attorney, Preet Bharara, United States Attorney for the Southern District of New York (“Government” or “Plaintiff”), by its undersigned counsel, states as follows:

1. Denies the allegations set forth in numbered paragraph 1 of the Complaint, except admits that the Government purports to bring this civil action against Novartis and BioScrip under the False Claims Act, 31 U.S.C. §§ 3729-3733 (the “FCA”), and the common law.
2. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 2 of the Complaint and denies the allegations set forth in the third sentence of numbered paragraph 2 of the Complaint. Because the first sentence of numbered paragraph 2 of the Complaint states conclusions or characterizations of law, no response is required.
3. Denies the allegations set forth in numbered paragraph 3 of the Complaint.
4. Denies the allegations set forth in numbered paragraph 4 of the Complaint.

5. Denies the allegations set forth in numbered paragraph 5 of the Complaint.
6. Denies the allegations set forth in numbered paragraph 6 of the Complaint.
7. Denies the allegations set forth in numbered paragraph 7 of the Complaint.
8. Denies the allegations set forth in numbered paragraph 8 of the Complaint.
9. Denies the allegations set forth in numbered paragraph 9 of the Complaint.
10. Denies the allegations set forth in numbered paragraph 10 of the Complaint.
11. Because numbered paragraph 11 of the Complaint states conclusions or characterizations of law, no response is required.
12. Denies knowledge or information sufficient to form a belief as to whether BioScrip transacts business in this District, and denies the other allegations set forth in numbered paragraph 12 of the Complaint, except admits that Novartis markets and sells brand name prescription medications within the geographic boundaries over which the United States District Court for the Southern District of New York presides. To the extent that numbered paragraph 12 of the Complaint states conclusions or characterizations of law, no response is required.
13. Admits the allegations set forth in numbered paragraph 13 of the Complaint.
14. Denies knowledge or information sufficient to form a belief as to the truth of what the Government alleges is “relevant here,” and otherwise admits the allegations set forth in numbered paragraph 14 of the Complaint.
15. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 15 of the Complaint. Denies the allegations set forth in the second sentence of numbered paragraph 15, except admits that BioScrip has distributed Exjade.

16. Because numbered paragraph 16 of the Complaint states conclusions or characterizations of law, no response is required.

17. Admits that the AKS contains the language quoted in numbered paragraph 17 of the Complaint and respectfully refers the Court to 42 U.S.C. § 1320a-7b for the entire text. To the extent that numbered paragraph 17 of the Complaint states conclusions or characterizations of law, no response is required.

18. Admits that the “Special Fraud Alerts” contain the language quoted in numbered paragraph 18 of the Complaint and respectfully refers the Court to the Federal Register for the entire text. To the extent that numbered paragraph 18 of the Complaint states conclusions or characterizations of law, no response is required.

19. Admits that the Code of Federal Regulations contains the language quoted in numbered paragraph 19 of the Complaint and respectfully refers the Court to 42 C.F.R. Part 1008 for the entire text. To the extent that numbered paragraph 19 of the Complaint states conclusions or characterizations of law, no response is required.

20. Admits that the FCA contains the language quoted in numbered paragraph 20 and respectfully refers the Court to 31 U.S.C. §§ 3729-3733 for the entire text. To the extent that numbered paragraph 20 and footnote numbers 1 and 2 of the Complaint state conclusions or characterizations of law, no response is required.

21. Admits that the AKS contains the language quoted in numbered paragraph 21 of the Complaint and respectfully refers the Court to 42 U.S.C. § 1320a-7b for the entire text, and admits that the PPACA was not enacted until 2010. To the extent that numbered paragraph 21 of the Complaint states conclusions or characterizations of law, no response is required.

22. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 22 of the Complaint, except admits that Medicare is a federal program that provides coverage of some healthcare services for persons who are 65 or older or are disabled, and respectfully refers the Court to 42 U.S.C. §§ 1395 *et seq.* and related regulations for a description of the program. To the extent that numbered paragraph 22 of the Complaint states conclusions or characterizations of law, no response is required.

23. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 23 of the Complaint. To the extent that numbered paragraph 23 of the Complaint states conclusions or characterizations of law, no response is required.

24. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 24 of the Complaint. To the extent that numbered paragraph 24 of the Complaint states conclusions or characterizations of law, no response is required.

25. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 25 of the Complaint.

26. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 26 of the Complaint. To the extent that numbered paragraph 26 of the Complaint states conclusions or characterizations of law, no response is required.

27. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 27 and footnote 3 of the Complaint. To the extent

that numbered paragraph 27 and footnote 3 of the Complaint state conclusions or characterizations of law, no response is required.

28. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 28 of the Complaint. To the extent that numbered paragraph 28 of the Complaint states conclusions or characterizations of law, no response is required.

29. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 29 of the Complaint. To the extent that numbered paragraph 29 of the Complaint states conclusions or characterizations of law, no response is required.

30. Admits that 42 C.F.R. § 423.505(k) contains the language quoted in numbered paragraph 30 of the Complaint, and respectfully refers the Court to that provision for a full and complete reading of its content. To the extent that numbered paragraph 30 of the Complaint states conclusions or characterizations of law, no response is required.

31. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 31 of the Complaint, except admits that the Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor contains the language quoted in numbered paragraph 31 of the Complaint, and respectfully refers the Court to that document for a full and complete reading of its content. To the extent that numbered paragraph 31 of the Complaint states conclusions or characterizations of law, no response is required.

32. Admits that 42 C.F.R. § 423.505(k)(3) contains the language quoted in numbered paragraph 32 of the Complaint, and respectfully refers the Court to that provision for a full and

complete reading of its content. To the extent that numbered paragraph 32 of the Complaint states conclusions or characterizations of law, no response is required.

33. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 33 of the Complaint, except admits that Medicaid is a joint federal-state program, and respectfully refers the Court to the relevant federal and state statutes and regulations for a description of the program. To the extent that numbered paragraph 33 of the Complaint states conclusions or characterizations of law, no response is required.

34. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 34 of the Complaint. To the extent that numbered paragraph 34 of the Complaint states conclusions or characterizations of law, no response is required.

35. Because numbered paragraph 35 of the Complaint states conclusions or characterizations of law, no response is required.

36. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 36 of the Complaint. To the extent that numbered paragraph 36 of the Complaint states conclusions or characterizations of law, no response is required.

37. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 37 of the Complaint, except admits that the eMedNY/MEDICAID MANAGEMENT INFORMATION SYSTEM CERTIFICATION STATEMENT FOR PROVIDER BILLING MEDICAID contains the language quoted in numbered paragraph 37 of the Complaint, and respectfully refers the Court to that document for

a full and complete reading of its content. To the extent that numbered paragraph 37 of the Complaint states conclusions or characterizations of law, no response is required.

38. Because the allegations set forth in numbered paragraph 38 of the Complaint state conclusions or characterizations of law, no response is required.

39. Because the allegations set forth in numbered paragraph 39 of the Complaint state conclusions or characterizations of law, no response is required.

40. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 40 of the Complaint. To the extent that numbered paragraph 40 of the Complaint states conclusions or characterizations of law, no response is required.

41. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 41 of the Complaint. To the extent that numbered paragraph 41 of the Complaint states conclusions or characterizations of law, no response is required.

42. Because the allegations set forth in numbered paragraph 42 of the Complaint state conclusions or characterizations of law, no response is required.

43. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 43 of the Complaint. To the extent that numbered paragraph 43 of the Complaint states conclusions or characterizations of law, no response is required.

44. Because the allegations set forth in numbered paragraph 44 of the Complaint state conclusions or characterizations of law, no response is required.

45. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 45 of the Complaint. To the extent that numbered paragraph 45 of the Complaint states conclusions or characterizations of law, no response is required.

46. Because the allegations set forth in numbered paragraph 46 of the Complaint state conclusions or characterizations of law, no response is required.

47. Because the allegations set forth in numbered paragraph 47 of the Complaint state conclusions or characterizations of law, no response is required.

48. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 48 of the Complaint. To the extent that numbered paragraph 48 of the Complaint states conclusions or characterizations of law, no response is required.

49. Because the allegations set forth in numbered paragraph 49 of the Complaint state conclusions or characterizations of law, no response is required.

50. Because the allegations set forth in numbered paragraph 50 of the Complaint state conclusions or characterizations of law, no response is required.

51. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 51 of the Complaint. To the extent that numbered paragraph 51 of the Complaint states conclusions or characterizations of law, no response is required.

52. Because the allegations set forth in numbered paragraph 52 of the Complaint state conclusions or characterizations of law, no response is required.



53. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 53 of the Complaint. To the extent that numbered paragraph 53 of the Complaint states conclusions or characterizations of law, no response is required.

54. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 54 of the Complaint. To the extent that numbered paragraph 54 of the Complaint states conclusions or characterizations of law, no response is required.

55. Because the allegations set forth in numbered paragraph 55 of the Complaint state conclusions or characterizations of law, no response is required.

56. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 56 of the Complaint. To the extent that numbered paragraph 56 of the Complaint states conclusions or characterizations of law, no response is required.

57. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 57 of the Complaint. To the extent that numbered paragraph 57 of the Complaint states conclusions or characterizations of law, no response is required.

58. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 58 of the Complaint. To the extent that numbered paragraph 58 of the Complaint states conclusions or characterizations of law, no response is required.

59. Because the allegations set forth in numbered paragraph 59 of the Complaint state conclusions or characterizations of law, no response is required.

60. Because the allegations set forth in numbered paragraph 60 of the Complaint state conclusions or characterizations of law, no response is required.

61. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 61 of the Complaint. To the extent that numbered paragraph 61 of the Complaint states conclusions or characterizations of law, no response is required.

62. Because the allegations set forth in numbered paragraph 62 of the Complaint state conclusions or characterizations of law, no response is required.

63. Because the allegations set forth in numbered paragraph 63 of the Complaint state conclusions or characterizations of law, no response is required.

64. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 64 of the Complaint. To the extent that numbered paragraph 64 of the Complaint states conclusions or characterizations of law, no response is required.

65. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 65 of the Complaint. To the extent that numbered paragraph 65 of the Complaint states conclusions or characterizations of law, no response is required.

66. Because the allegations set forth in numbered paragraph 66 of the Complaint state conclusions or characterizations of law, no response is required.

67. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 67 of the Complaint. To the extent that numbered paragraph 67 of the Complaint states conclusions or characterizations of law, no response is required.

68. Because the allegations set forth in numbered paragraph 68 of the Complaint state conclusions or characterizations of law, no response is required.

69. Because the allegations set forth in numbered paragraph 69 of the Complaint state conclusions or characterizations of law, no response is required.

70. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 70 of the Complaint. To the extent that numbered paragraph 70 of the Complaint states conclusions or characterizations of law, no response is required.

71. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 71 of the Complaint. To the extent that numbered paragraph 71 of the Complaint states conclusions or characterizations of law, no response is required.

72. Because the allegations set forth in numbered paragraph 72 of the Complaint state conclusions or characterizations of law, no response is required.

73. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 73 of the Complaint. To the extent that numbered paragraph 73 of the Complaint states conclusions or characterizations of law, no response is required.

74. Because the allegations set forth in numbered paragraph 74 of the Complaint state conclusions or characterizations of law, no response is required.

75. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 75 of the Complaint. To the extent that numbered paragraph 75 of the Complaint states conclusions or characterizations of law, no response is required.

76. Because the allegations set forth in numbered paragraph 76 of the Complaint state conclusions or characterizations of law, no response is required.

77. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 77 of the Complaint. To the extent that numbered paragraph 77 of the Complaint states conclusions or characterizations of law, no response is required.

78. Because the allegations set forth in numbered paragraph 78 of the Complaint state conclusions or characterizations of law, no response is required.

79. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 79 of the Complaint. To the extent that numbered paragraph 79 of the Complaint states conclusions or characterizations of law, no response is required.

80. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 80 of the Complaint. To the extent that numbered paragraph 80 of the Complaint states conclusions or characterizations of law, no response is required.

81. Because the allegations set forth in numbered paragraph 81 of the Complaint state conclusions or characterizations of law, no response is required.

82. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 82 of the Complaint. To the extent that numbered paragraph 82 of the Complaint states conclusions or characterizations of law, no response is required.

83. Because the allegations set forth in numbered paragraph 83 of the Complaint state conclusions or characterizations of law, no response is required.

84. Because the allegations set forth in numbered paragraph 84 of the Complaint state conclusions or characterizations of law, no response is required.

85. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 85 of the Complaint. To the extent that numbered paragraph 85 of the Complaint states conclusions or characterizations of law, no response is required.

86. Because the allegations set forth in numbered paragraph 86 of the Complaint state conclusions or characterizations of law, no response is required.

87. Because the allegations set forth in numbered paragraph 87 of the Complaint state conclusions or characterizations of law, no response is required.

88. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 88 of the Complaint. To the extent that numbered paragraph 88 of the Complaint states conclusions or characterizations of law, no response is required.

89. Because the allegations set forth in numbered paragraph 89 of the Complaint state conclusions or characterizations of law, no response is required.

90. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 90 of the Complaint. To the extent that numbered paragraph 90 of the Complaint states conclusions or characterizations of law, no response is required.

91. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 91 of the Complaint. To the extent that numbered paragraph 91 of the Complaint states conclusions or characterizations of law, no response is required.

92. Because the allegations set forth in numbered paragraph 92 of the Complaint state conclusions or characterizations of law, no response is required.

93. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 93 of the Complaint. To the extent that numbered paragraph 93 of the Complaint states conclusions or characterizations of law, no response is required.

94. Because the allegations set forth in numbered paragraph 94 of the Complaint state conclusions or characterizations of law, no response is required.

95. Because the allegations set forth in numbered paragraph 95 of the Complaint state conclusions or characterizations of law, no response is required.

96. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 96 of the Complaint. To the extent that numbered

paragraph 96 of the Complaint states conclusions or characterizations of law, no response is required.

97. Because the allegations set forth in numbered paragraph 97 of the Complaint state conclusions or characterizations of law, no response is required.

98. Because the allegations set forth in numbered paragraph 98 of the Complaint state conclusions or characterizations of law, no response is required.

99. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 99 of the Complaint. To the extent that numbered paragraph 99 of the Complaint states conclusions or characterizations of law, no response is required.

100. Because the allegations set forth in numbered paragraph 100 of the Complaint state conclusions or characterizations of law, no response is required.

101. Because the allegations set forth in numbered paragraph 101 of the Complaint state conclusions or characterizations of law, no response is required.

102. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 102 of the Complaint. To the extent that numbered paragraph 102 of the Complaint states conclusions or characterizations of law, no response is required.

103. Because the allegations set forth in numbered paragraph 103 of the Complaint state conclusions or characterizations of law, no response is required.

104. Because the allegations set forth in numbered paragraph 104 of the Complaint state conclusions or characterizations of law, no response is required.

105. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 105 of the Complaint. To the extent that numbered paragraph 105 of the Complaint states conclusions or characterizations of law, no response is required.

106. Because the allegations set forth in numbered paragraph 106 of the Complaint state conclusions or characterizations of law, no response is required.

107. Because the allegations set forth in numbered paragraph 107 of the Complaint state conclusions or characterizations of law, no response is required.

108. Because the allegations set forth in numbered paragraph 108 of the Complaint state conclusions or characterizations of law, no response is required.

109. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 109 of the Complaint. To the extent that numbered paragraph 109 of the Complaint states conclusions or characterizations of law, no response is required.

110. Because the allegations set forth in numbered paragraph 110 of the Complaint state conclusions or characterizations of law, no response is required.

111. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 111 of the Complaint. To the extent that numbered paragraph 111 of the Complaint states conclusions or characterizations of law, no response is required.

112. Because the allegations set forth in numbered paragraph 112 of the Complaint state conclusions or characterizations of law, no response is required.



113. Because the allegations set forth in numbered paragraph 113 of the Complaint state conclusions or characterizations of law, no response is required.

114. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 114 of the Complaint. To the extent that numbered paragraph 114 of the Complaint states conclusions or characterizations of law, no response is required.

115. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 115 of the Complaint. To the extent that numbered paragraph 115 of the Complaint states conclusions or characterizations of law, no response is required.

116. Because the allegations set forth in numbered paragraph 116 of the Complaint state conclusions or characterizations of law, no response is required.

117. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 117 of the Complaint. To the extent that numbered paragraph 117 of the Complaint states conclusions or characterizations of law, no response is required.

118. Because the allegations set forth in numbered paragraph 118 of the Complaint state conclusions or characterizations of law, no response is required.

119. Denies the allegations set forth in the first sentence of numbered paragraph 119 of the Complaint, except admits that Myfortic is a delayed-release antimetabolite immunosuppressant tablet indicated for prophylaxis of organ rejection in adult patients receiving kidney transplants and in pediatric patients at least 5 years of age and older who are at least 6 months post kidney transplant, to be used in combination with cyclosporine and corticosteroids.

Denies the allegations set forth in the second and third sentences of numbered paragraph 119 of the Complaint, except admits that, at times, various Novartis employees have negotiated rebate and discount contracts with pharmacies and transplant centers, promoted Myfortic to transplant physicians and created marketing materials for Myfortic.

120. Denies the allegations set forth in numbered paragraph 120 of the Complaint, except admits that Novartis makes Myfortic available for sale to pharmacies through wholesalers and that pharmacies that dispense Myfortic to patients may submit reimbursement claims to the patients' insurers, including Medicare and Medicaid.

121. Denies the allegations set forth in numbered paragraph 121 and footnote number 4 of the Complaint, except admits that certain Myfortic prescriptions may be eligible for reimbursement under Medicaid and/or Medicare Parts B and D, and respectfully refers the Court to 42 U.S.C. §§ 1396r-8 for a full and complete reading of its provisions. To the extent that numbered paragraph 121 and footnote number 4 of the Complaint state conclusions or characterizations of law, no response is required.

122. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the third sentence of numbered paragraph 122 of the Complaint, denies that the price of branded CellCept and Myfortic were "generally comparable," and denies the allegations set forth in the first two sentences of numbered paragraph 122 of the Complaint, except admits that CellCept is a brand-name drug in the same therapeutic class as Myfortic and that generic versions of CellCept, which have been available since 2009, are generally priced lower than both branded CellCept and Myfortic.

123. Denies the allegations set forth in the first and second sentences of numbered paragraph 123 of the Complaint, except admits that BioScrip has dispensed Exjade. Denies

knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the third sentence of numbered paragraph 123 of the Complaint.

124. Denies the allegations set forth in numbered paragraph 124 of the Complaint.

125. Denies the allegations set forth in numbered paragraph 125 of the Complaint, except admits that certain contracts executed by Novartis provide a Medicare Part B Utilization Performance Benefit to pharmacies for achieving certain utilization benchmarks in relation to Myfortic, as specified therein.

126. Denies the allegations set forth in numbered paragraph 126 of the Complaint, except admits that a Novartis employee sent an e-mail on October 16, 2009 regarding contract negotiations with Bryant's Pharmacy, and respectfully refers the Court to that e-mail.

127. Denies the allegations set forth in numbered paragraph 127 of the Complaint, except admits that it has paid millions of dollars in rebates to state Medicaid agencies in connection with the dispensing of Myfortic to Medicaid patients over the time period referenced in the Government's Complaint.

128. Denies the allegations set forth in numbered paragraph 128 of the Complaint, except admits that a Novartis employee prepared a monthly report dated March 2010 regarding Twenty-Ten Pharmacy, and respectfully refers the Court to the report.

129. Denies the allegations set forth in numbered paragraph 129 of the Complaint, except admits that a Novartis employee prepared a report entitled "Exjade EPASS Network" regarding adherence to Exjade, and that a BioScrip presentation to Novartis dated September 14, 2009 addressed Exjade therapy management, and respectfully refers the Court to those documents.

130. Admits that there exists Novartis Pharma Principles & Practices for Professionals that includes the language quoted in numbered paragraph 130, and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 130 of the Complaint.

131. Admits that Novartis Ethics and Compliance (“E&C”) Policies contain the language quoted in numbered paragraph 131 and respectfully refers the Court to that document for a full and complete reading of its content.

132. Admits that Novartis’s internal policies include Novartis E&C Policies that include the language quoted in numbered paragraph 132 and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 132 of the Complaint.

133. Admits that Novartis E&C Policies contain the language quoted in numbered paragraph 133 and respectfully refers the Court to that document for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 133 of the Complaint.

134. Admits that Novartis has fully complied with the AKS and its own internal policies in connection with the sale, promotion and marketing of Myfortic, and is further unable to respond because the allegation in numbered paragraph 134 lacks any information about the identities of the referenced executives.

135. Admits that, in September 2010, Novartis entered into a settlement agreement with the Government and several Relators to resolve civil claims brought by the Government, the Relators and certain states regarding Novartis’s promotion of certain drugs and that Novartis entered into a separate plea agreement with the Government with respect to an information

brought by the Government regarding Novartis's alleged off label promotion of one drug, and respectfully refers the Court to those documents for a full and complete reading of their content, and denies the remaining allegations set forth in numbered paragraph 135 of the Complaint.

136. Admits the allegations set forth in numbered paragraph 136 of the Complaint, and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content.

137. Admits that the Novartis CIA contains the language quoted in numbered paragraph 137 of the Complaint and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content.

138. Admits that the Novartis CIA includes various certification provisions and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 138 of the Complaint.

139. Admits that the Novartis CIA includes various notification provisions and respectfully refers the Court to the Novartis CIA for a full and complete reading of its content, and denies the remaining allegations set forth in numbered paragraph 139 of the Complaint.

140. Denies the allegations set forth in numbered paragraph 140 of the Complaint.

141. Denies the allegations set forth in numbered paragraph 141 of the Complaint.

142. Denies the allegations set forth in numbered paragraph 142 of the Complaint.

143. Denies the allegations set forth in numbered paragraph 143 of the Complaint.

144. Denies the allegations set forth in numbered paragraph 144 of the Complaint, except admits that, on January 29, 2010, a Novartis employee sent an e-mail to the director of the outpatient pharmacy at Baylor University Medical Center regarding Myfortic, and respectfully refers the Court to that e-mail.

145. Denies the allegations set forth in numbered paragraph 145 of the Complaint.

146. Denies the allegations set forth in numbered paragraph 146 of the Complaint.

147. Denies the allegations set forth in numbered paragraph 147 of the Complaint.

148. Denies the allegations set forth in numbered paragraph 148 of the Complaint.

149. Denies the allegations set forth in numbered paragraph 149 of the Complaint.

150. Denies the allegations set forth in numbered paragraph 150 of the Complaint.

151. Denies the allegations set forth in numbered paragraph 151 of the Complaint.

152. Denies the allegations set forth in numbered paragraph 152 of the Complaint.

153. Denies the allegations set forth in numbered paragraph 153 of the Complaint.

154. Denies the allegations set forth in numbered paragraph 154 of the Complaint.

155. Denies the allegations set forth in numbered paragraph 155 of the Complaint.

156. Denies the allegations set forth in numbered paragraph 156 of the Complaint.

157. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 157 of the Complaint.

158. Denies the allegations set forth in the first and third sentences of numbered paragraph 158 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 158 of the Complaint.

159. Denies the allegations set forth in numbered paragraph 159 of the Complaint, except admits that, on October 16, 2009, a Novartis employee sent an e-mail to other Novartis employees regarding Bryant's Pharmacy, and that, in December 2009, Novartis amended its June 1, 2007 agreement with Bryant's Pharmacy, effective October 1, 2009, and respectfully refers the Court to that e-mail and amendment.

160. Denies the allegations set forth in numbered paragraph 160 of the Complaint.

161. Denies the allegations set forth in numbered paragraph 161 of the Complaint.

162. Denies the allegations set forth in numbered paragraph 162 of the Complaint.

163. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 163 of the Complaint and denies the allegations set forth in the second and third sentences of numbered paragraph 163 of the Complaint.

164. Denies the allegations set forth in numbered paragraph 164 of the Complaint.

165. Denies the allegations set forth in numbered paragraph 165 of the Complaint.

166. Denies the allegations set forth in numbered paragraph 166 of the Complaint.

167. Denies the allegations set forth in numbered paragraph 167 of the Complaint.

168. Denies the allegations set forth in numbered paragraph 168 of the Complaint.

169. Denies the allegations set forth in numbered paragraph 169 of the Complaint.

170. Denies the allegations set forth in numbered paragraph 170 of the Complaint.

171. Denies the allegations set forth in numbered paragraph 171 of the Complaint.

172. Denies the allegations set forth in numbered paragraph 172 of the Complaint.

173. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 173 of the Complaint and denies the allegations set forth in the second sentence of numbered paragraph 173 of the Complaint.

174. Denies the allegations set forth in numbered paragraph 174 of the Complaint, except admits that, on March 22, 2011, Novartis received an e-mail from the President of Kilgore regarding Myfortic, and respectfully refers the Court to that e-mail.

175. Denies the allegations set forth in numbered paragraph 175 of the Complaint.

176. Denies the allegations set forth in numbered paragraph 176 of the Complaint.

177. Denies the allegations set forth in numbered paragraph 177 of the Complaint.

178. Denies the allegations set forth in numbered paragraph 178 of the Complaint.

179. Denies the allegations set forth in numbered paragraph 179 of the Complaint.

180. Denies the allegations set forth in numbered paragraph 180 of the Complaint.

181. Denies the allegations set forth in numbered paragraph 181 of the Complaint.

182. Denies the allegations set forth in numbered paragraph 182 of the Complaint.

183. Denies the allegations set forth in numbered paragraph 183 of the Complaint.

184. Denies the allegations set forth in numbered paragraph 184 of the Complaint.

185. Denies the allegations set forth in numbered paragraph 185 of the Complaint.

186. Denies the allegations set forth in the first sentence of numbered paragraph 186 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second, third and fourth sentences of numbered paragraph 186 of the Complaint.

187. Denies the allegations set forth in numbered paragraph 187 of the Complaint.

188. Denies the allegations set forth in numbered paragraph 188 of the Complaint.

189. Denies the allegations set forth in numbered paragraph 189 of the Complaint.

190. Denies the allegations set forth in the first sentence of numbered paragraph 190 of the Complaint and denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second and third sentences of numbered paragraph 190 of the Complaint.

191. Denies the allegations set forth in numbered paragraph 191 of the Complaint, except admits that, since 2004, Novartis has entered into certain agreements involving Twenty-



Ten Pharmacy, and respectfully refers the Court to those agreements for a full and complete reading of their content.

192. Denies the allegations set forth in numbered paragraph 192 of the Complaint.

193. Denies the allegations set forth in numbered paragraph 193 of the Complaint.

194. Denies the allegations set forth in numbered paragraph 194 of the Complaint.

195. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 195 of the Complaint as to Twenty-Ten, and denies the allegations set forth in the second sentence of numbered paragraph 195 of the Complaint, except admits that, on April 5, 2010, a Novartis employee sent an e-mail to her supervisor regarding Twenty-Ten Pharmacy, and respectfully refers the Court to that e-mail.

196. Denies the allegations set forth in numbered paragraph 196 of the Complaint.

197. Denies the allegations set forth in numbered paragraph 197 of the Complaint.

198. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the first sentence of numbered paragraph 198 of the Complaint and denies the allegations set forth in the second and third sentences of numbered paragraph 198 of the Complaint.

199. Denies the allegations set forth in the first sentence of numbered paragraph 199 of the Complaint and denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 199 of the Complaint.

200. Denies the allegations set forth in numbered paragraph 200 of the Complaint.

201. Denies the allegations set forth in numbered paragraph 201 of the Complaint.

202. Denies the allegations set forth in numbered paragraph 202 of the Complaint.

203. Denies the allegations set forth in numbered paragraph 203 of the Complaint.

204. Denies the allegations set forth in numbered paragraph 204 of the Complaint.

205. Denies the allegations set forth in numbered paragraph 205 of the Complaint.

206. Denies the allegations set forth in numbered paragraph 206 of the Complaint, except admits that, on October 29, 2009, a Novartis employee sent an e-mail to several other Novartis employees regarding Myfortic contracting, and respectfully refers the Court to that e-mail.

207. Denies the allegations set forth in numbered paragraph 207 of the Complaint.

208. Denies the allegations set forth in numbered paragraph 208 of the Complaint.

209. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 209 of the Complaint and states that it has fully complied with the AKS and its own internal policies in connection with the sale, promotion and marketing of Myfortic. To the extent that numbered paragraph 209 of the Complaint states conclusions or characterizations of law, no response is required.

210. Denies the allegations set forth in numbered paragraph 210 of the Complaint.

211. Denies the allegations set forth in numbered paragraph 211 of the Complaint.

212. Denies the allegations set forth in numbered paragraph 212 of the Complaint.

213. Denies the allegations set forth in numbered paragraph 213 of the Complaint.

214. Denies the allegations set forth in numbered paragraph 214 of the Complaint.

215. Denies the allegations set forth in numbered paragraph 215 of the Complaint, except admits that, on February 25, 2011, a Novartis employee sent an e-mail to several other Novartis employees regarding Walgreen's, and respectfully refers the Court to that e-mail.

216. Denies the allegations set forth in numbered paragraph 216 of the Complaint, except admits that, on February 25, 2011, a Novartis employee sent an e-mail to several other Novartis employees regarding Walgreen's, and respectfully refers the Court to that e-mail.

217. Denies the allegations set forth in numbered paragraph 217 of the Complaint.

218. Denies the allegations set forth in numbered paragraph 218 of the Complaint, except admits that Novartis has internal policies regarding raising compliance concerns with the company, and respectfully refers the Court to those policies for a full and complete reading of their content.

219. Denies the allegations set forth in numbered paragraph 219 of the Complaint.

220. Denies the allegations set forth in numbered paragraph 220 of the Complaint.

221. Denies the allegations set forth in numbered paragraph 221 of the Complaint.

222. Denies the allegations set forth in numbered paragraph 222 of the Complaint.

223. Denies the allegations set forth in numbered paragraph 223 of the Complaint.

224. Denies the allegations set forth in numbered paragraph 224 of the Complaint.

225. Denies the allegations set forth in numbered paragraph 225 of the Complaint.

226. Denies the allegations set forth in the first, second and third sentences of numbered paragraph 226 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the fourth sentence of numbered paragraph 226.

227. Denies the allegations set forth in numbered paragraph 227 of the Complaint.

228. Denies the allegations set forth in numbered paragraph 228 of the Complaint.

229. Denies the allegations set forth in numbered paragraph 229 of the Complaint.

230. Denies the allegations set forth in numbered paragraph 230 of the Complaint.

231. Admits the allegations set forth in numbered paragraph 231, and respectfully refers the Court to the 2005 Exjade label for a full and complete reading of its content.

232. Denies the first sentence of numbered paragraph 232 of the Complaint, except admits that the FDA approved Exjade under 21 C.F.R. § 314.510, and respectfully refers the Court to that provision for a full and complete reading of its content. Because the second and third sentences of numbered paragraph 232 of the Complaint state conclusions or characterizations of law, no response is required.

233. Admits the allegation set forth in the first sentence of numbered paragraph 233 of the Complaint. Denies the second sentence of numbered paragraph 233 of the Complaint, except admits that Exjade is prescribed for patients with beta-thalassemia, sickle cell disease and myelodysplastic syndrome.

234. Denies the allegations set forth in numbered paragraph 234 of the Complaint.

235. Denies the allegations set forth in numbered paragraph 235 of the Complaint, and respectfully refers the Court to the 2005 Exjade label for a full and complete reading of its content.

236. Denies the allegations set forth in numbered paragraph 236 of the Complaint.

237. Denies the allegations set forth in numbered paragraph 237 of the Complaint, except admits that text regarding warnings and precautions was added to the Exjade labels, and respectfully refers the Court to the Exjade labels referenced in the Complaint for a full and complete reading of their content.

238. Denies the allegations set forth in numbered paragraph 238 of the Complaint, but admits that the 2010 version of the Exjade label contains a boxed warning, and respectfully refers the Court to that warning for a full and complete reading of its content. Because footnote

number 5 in numbered paragraph 238 of the Complaint states conclusions or characterizations of law, no response is required.

239. Denies the allegations set forth in numbered paragraph 239, but admits that Novartis submitted responses to the FDA on July 8, 2009 and October 14, 2009, and respectfully refers the court to those responses.

240. Denies the allegations set forth in numbered paragraph 240, except admits that the 2010 Exjade label contains a boxed warning, and respectfully refers the Court to the language of the boxed warning in the January 2010 Exjade label for a full and complete reading of its content.

241. Denies the allegations set forth in numbered paragraph 241 of the Complaint, except admits EPASS was a distribution network that included three pharmacies that dispensed Exjade.

242. Denies the allegations set forth in numbered paragraph 242 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

243. Denies the allegations set forth in numbered paragraph 243 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

244. Denies the allegations set forth in numbered paragraph 244 and footnote 6 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

245. Denies the allegations set forth in numbered paragraph 245 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

246. Denies the allegations set forth in numbered paragraph 246 of the Complaint, except admits that Novartis and BioScrip entered into a contract that became effective as of November 21, 2005, and respectfully refers the Court to that contract.

247. Denies the allegations set forth in numbered paragraph 247 of the Complaint.

248. Denies the allegations set forth in numbered paragraph 248 of the Complaint.

249. Denies the allegations set forth in numbered paragraph 249 of the Complaint.

250. Denies the allegations set forth in numbered paragraph 250 and footnote 7 of the Complaint.

251. Denies the allegations set forth in numbered paragraph 251 of the Complaint.

252. Denies the allegations set forth in numbered paragraph 252 of the Complaint.

253. Denies the allegations set forth in numbered paragraph 253 of the Complaint.

254. Denies the allegations set forth in numbered paragraph 254 of the Complaint.

255. Denies the allegations set forth in numbered paragraph 255 of the Complaint.

256. Denies the allegations set forth in numbered paragraph 256 of the Complaint.

257. Denies the allegations set forth in numbered paragraph 257 of the Complaint.

258. Denies the allegations set forth in numbered paragraph 258 of the Complaint.

259. Denies the allegations set forth in numbered paragraph 259 of the Complaint.

260. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 260 of the Complaint.

261. Denies the allegations set forth in numbered paragraph 261 of the Complaint.

262. Denies the allegations set forth in numbered paragraph 262 of the Complaint.

263. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 263 of the Complaint.

264. Denies the allegations set forth in numbered paragraph 264 of the Complaint.

265. Denies the allegations set forth in numbered paragraph 265 of the Complaint.

266. Denies the allegations set forth in numbered paragraph 266 of the Complaint.

267. Denies the allegations set forth in numbered paragraph 267 of the Complaint.

268. Denies the allegations set forth in numbered paragraph 268 of the Complaint.

269. Denies the allegations set forth in numbered paragraph 269 of the Complaint.

270. Denies the allegations set forth in numbered paragraph 270 of the Complaint.

271. Denies the allegations set forth in numbered paragraph 271 of the Complaint, except admits that a contractual amendment was executed in June 2008, and respectfully refers the Court to that amendment.

272. Denies the allegations set forth in numbered paragraph 272 of the Complaint.

273. Denies the allegations set forth in numbered paragraph 273 of the Complaint.

274. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 274 of the Complaint.

275. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 275 of the Complaint.

276. Denies the allegations set forth in numbered paragraph 276 of the Complaint.

277. Denies the allegations set forth in numbered paragraph 277 of the Complaint.

278. Denies the allegations set forth in numbered paragraph 278 of the Complaint.

279. Denies the allegations set forth in numbered paragraph 279 of the Complaint.

280. Denies the allegations set forth in numbered paragraph 280 of the Complaint.

281. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 281 of the Complaint.

282. Denies the allegations set forth in the first sentence of numbered paragraph 282 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second, third and fourth sentences of numbered paragraph 282 of the Complaint.

283. Denies the allegations set forth in numbered paragraph 283 of the Complaint.

284. Denies the allegations set forth in numbered paragraph 284 of the Complaint.

285. Denies the allegations set forth in numbered paragraph 285 of the Complaint.

286. Denies the allegations set forth in numbered paragraph 286 of the Complaint.

287. Denies the allegations set forth in numbered paragraph 287 of the Complaint.

288. Denies the allegations set forth in the first and third sentences of numbered paragraph 288 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 288 of the Complaint.

289. Denies the allegations set forth in numbered paragraph 289 of the Complaint.

290. Denies the allegations set forth in numbered paragraph 290 of the Complaint.

291. Denies the allegations set forth in the first, second, third, fourth and fifth sentences of numbered paragraph 291 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the sixth sentence of numbered paragraph 291 of the complaint.



292. Denies the allegations set forth in numbered paragraph 292 of the Complaint, except admits that the 2010 version of the Exjade label contains a boxed warning, and respectfully refers the Court to that warning for a full and complete reading of its content.

293. Denies the allegations set forth in numbered paragraph 293, except admits that Novartis submitted responses to the FDA on July 8, 2009 and October 14, 2009, and respectfully refers the court to those responses.

294. Denies the allegations set forth in the first sentence of numbered paragraph 294 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 294 of the Complaint.

295. Denies the allegations set forth in numbered paragraph 295 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of numbered paragraph 295 of the Complaint.

296. Denies the allegations set forth in numbered paragraph 296 and footnote 8 of the Complaint, and respectfully refers the Court to the cited deposition for a full and complete reading of its content.

297. Denies the allegations set forth in numbered paragraph 297 of the Complaint.

298. Denies the allegations set forth in numbered paragraph 298 of the Complaint, except admits that Novartis had a contractual relationship with BioScrip since 2005, and respectfully refers the Court to those contracts.

299. Denies the allegations set forth in numbered paragraph 299 of the Complaint.

300. Denies the allegations set forth in numbered paragraph 300 of the Complaint.

301. Denies the allegations set forth in numbered paragraph 301 of the Complaint.

302. Denies the allegations set forth in numbered paragraph 302 of the Complaint.

303. Denies the allegations set forth in numbered paragraph 303 of the Complaint, and respectfully refers the Court to the referenced contracts.

304. Denies the allegations set forth in numbered paragraph 304 of the Complaint.

305. Denies the allegations set forth in numbered paragraph 305 of the Complaint.

306. Denies the allegations set forth in numbered paragraph 306 of the Complaint.

307. Denies the allegations set forth in numbered paragraph 307 of the Complaint. To the extent that numbered paragraph 307 of the Complaint states conclusions or characterizations of law, no response is required.

308. Denies the allegations set forth in numbered paragraph 308 of the Complaint. To the extent that numbered paragraph 308 of the Complaint states conclusions or characterizations of law, no response is required.

309. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 309 of the Complaint.

310. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 310 and footnote 9 of the Complaint.

311. Denies the allegations set forth in numbered paragraph 311 of the Complaint.

### **FIRST CLAIM**

#### **Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729 (a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A))**

312. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

313. Because numbered paragraph 313 of the Complaint states conclusions or characterizations of law, no response is required.

314. Denies the allegations set forth in numbered paragraph 314 of the Complaint.

315. Denies the allegations set forth in numbered paragraph 315 of the Complaint.

316. Denies the allegations set forth in numbered paragraph 316 of the Complaint.

### **SECOND CLAIM**

#### **Violations of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(2)(2000) and, as amended, 31 U.S.C. § (a)(1)(B)(Supp. 2009))**

317. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

318. Because numbered paragraph 318 of the Complaint states conclusions or characterizations of law, no response is required.

319. Denies the allegations set forth in numbered paragraph 319 of the Complaint.

320. Denies the allegations set forth in numbered paragraph 320 of the Complaint and respectfully refers the Court to 31 U.S.C. § 3729(a)(1)(B) for a full and complete reading of its provisions. To the extent that numbered paragraph 320 of the Complaint states conclusions or characterizations of law, no response is required.

321. Denies the allegations set forth in numbered paragraph 321 of the Complaint.

### **THIRD CLAIM**

#### **Violations of the False Claims Act: Conspiring to Violate the False Claims Act (31 U.S.C. § 3729 (a)(3)(1986) and, as amended, 31 U.S.C. § 3729 (a)(1)(C))**

322. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

323. Because numbered paragraph 323 of the Complaint states conclusions or characterizations of law, no response is required.

324. Denies the allegations set forth in numbered paragraph 324 of the Complaint.

325. Denies the allegations set forth in numbered paragraph 325 of the Complaint.

326. Denies the allegations set forth in numbered paragraph 326 of the Complaint.

**FOURTH CLAIM**

**Unjust Enrichment**

327. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

328. Denies the allegations set forth in numbered paragraph 328 of the Complaint.

329. Denies the allegations set forth in numbered paragraph 329 of the Complaint.

330. Denies the allegations set forth in numbered paragraph 330 of the Complaint.

**FIFTH CLAIM**

**Violations of the False Claims Act: Presenting False Claims for Payment  
(31 U.S.C. § 3729 (a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A))**

331. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

332. Because numbered paragraph 332 of the Complaint states conclusions or characterizations of law, no response is required.

333. Denies the allegations set forth in numbered paragraph 333 of the Complaint.

334. Denies the allegations set forth in numbered paragraph 334 of the Complaint.

335. Denies the allegations set forth in numbered paragraph 335 of the Complaint.

**SIXTH CLAIM**

**Violations of the False Claims Act: Use of False Statements  
(31 U.S.C. § 3729(a)(2)(2000) and, as amended, 31 U.S.C. § (a)(1)(B)(Supp. 2009))**

336. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

337. Because numbered paragraph 337 of the Complaint states conclusions or characterizations of law, no response is required.

338. Denies the allegations set forth in numbered paragraph 338 of the Complaint.

339. Denies the allegations set forth in numbered paragraph 339 of the Complaint and respectfully refers the Court to 31 U.S.C. § 3729(a)(1)(B) for a full and complete reading of its provisions. To the extent that numbered paragraph 339 of the Complaint states conclusions or characterizations of law, no response is required.

340. Denies the allegations set forth in numbered paragraph 340 of the Complaint.

#### **SEVENTH CLAIM**

##### **Violations of the False Claims Act: Conspiring to Violate the False Claims Act (31 U.S.C. § 3729 (a)(3)(1986) and, as amended, 31 U.S.C. § 3729 (a)(1)(C))**

341. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

342. Because numbered paragraph 342 of the Complaint states conclusions or characterizations of law, no response is required.

343. Denies the allegations set forth in numbered paragraph 343 of the Complaint.

344. Denies the allegations set forth in numbered paragraph 344 of the Complaint.

345. Denies the allegations set forth in numbered paragraph 345 of the Complaint.

#### **EIGHTH CLAIM**

##### **Unjust Enrichment**

346. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

347. Denies the allegations set forth in numbered paragraph 347 of the Complaint.

348. Denies the allegations set forth in numbered paragraph 348 of the Complaint.

349. Denies the allegations set forth in numbered paragraph 349 of the Complaint.

**NINTH CLAIM**

**Payment by Mistake of Fact**

350. Novartis repeats and incorporates by reference its responses to numbered paragraphs 1 through 311 above.

351. Denies the allegations set forth in numbered paragraph 351 of the Complaint.

352. Denies the allegations set forth in numbered paragraph 352 of the Complaint.

**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

The Government fails to state a claim against Novartis upon which relief may be granted, and the Complaint should be dismissed.

**SECOND AFFIRMATIVE DEFENSE**

The Government fails to allege any false claim under the False Claims Act because Novartis's conduct did not result in any "false or fraudulent claim" in violation of 31 U.S.C. § 3729(a).

**THIRD AFFIRMATIVE DEFENSE**

The Government fails to allege that any claim submitted by a pharmacy prior to March 2010 was a false or fraudulent claim under the FCA because those claims did not contain or otherwise incorporate express or implied statements that were false or fraudulent as a result of the conduct alleged against Novartis.

**FOURTH AFFIRMATIVE DEFENSE**

The Government's claims fail because the rebate payments, discounts and the patient allocations at issue are not unlawful kickbacks under 42 U.S.C. § 1320a-7b.

**FIFTH AFFIRMATIVE DEFENSE**

The Government's claims fail because the rebate payments and discounts at issue are protected under the statutory exception for discounts provided for in 42 U.S.C. § 1320a-7b(b)(3)(A).

**SIXTH AFFIRMATIVE DEFENSE**

The Government's claims fail because the rebate payments and discounts at issue are protected under the regulatory exceptions (safe harbors) for discounts provided for in 42 C.F.R. § 1001.952(h).

**SEVENTH AFFIRMATIVE DEFENSE**

The Government's claims fail because, at all times relevant hereto, Novartis complied with all applicable federal and state regulations.

**EIGHTH AFFIRMATIVE DEFENSE**

The Government's claims are barred, in whole or in part, because they rely upon ambiguous provisions of the False Claims Act and other provisions of law, and the rule of lenity requires such ambiguities to be construed in Novartis's favor.

**NINTH AFFIRMATIVE DEFENSE**

The Government's claims are barred, in whole or in part, because they violate Novartis's rights under the Due Process and Ex Post Facto clauses of the United States Constitution, insofar as the Government seeks to impose liability retroactively for conduct that is not prohibited by federal statutes or regulations.

**TENTH AFFIRMATIVE DEFENSE**

The Government's claims fail because any and all actions taken by Novartis with respect to any of the matters alleged in the Complaint were taken in accordance with established industry practice.

**ELEVENTH AFFIRMATIVE DEFENSE**

The Government's claims are barred, in whole or in part, due to its failure to join indispensable parties.

**TWELFTH AFFIRMATIVE DEFENSE**

The Government's claims are barred, in whole or in part, by the applicable statutes of limitations and repose.

**THIRTEENTH AFFIRMATIVE DEFENSE**

The Government's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that the Government, through the Medicare and Medicaid programs, has reimbursed specialty pharmacy providers for dispensing Myfortic to Medicare and Medicaid beneficiaries after the filing of the Complaint.

**FOURTEENTH AFFIRMATIVE DEFENSE**

The Government's claims are barred, in whole or in part, by the doctrines of laches, estoppel and waiver.

**FIFTEENTH AFFIRMATIVE DEFENSE**

The Government's claims for damages are barred or should be reduced based on the Government's failure to mitigate damages.



**SIXTEENTH AFFIRMATIVE DEFENSE**

The Government's claims fail because, to the extent that it attempts to seek equitable relief against Novartis, the Government is not entitled to such relief because it has an adequate remedy at law.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

The Government's claims fail because, to the extent civil penalties are sought against Novartis, such civil penalties cannot be sustained because an award of civil penalties would violate the Excessive Fines Clause of the Eighth Amendment and the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

The Government's claims fail because, to the extent that the Government is alleging fraud or similar conduct, it has failed to plead fraud with particularity.

**NINETEENTH AFFIRMATIVE DEFENSE**

The Government's claims fail because its federal common law unjust enrichment claims are displaced by statute.

**TWENTIETH AFFIRMATIVE DEFENSE**

The Government's claims fail because they are too remote and speculative to form the basis for relief.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

The Government's claims fail because it has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Novartis as alleged in the Complaint.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

The Government's claims are barred, in whole or in part, because the Government's injuries were not proximately caused by the acts or omissions of Novartis, but, if they exist at all, were the result in whole or in part of intervening or supervening causes.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

To the extent the Government obtains or obtained recovery in any other proceeding predicated on the same factual allegations, the Government is barred from seeking recovery against Novartis based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Novartis reserves the rights to raise any additional defenses, cross-claims and third party claims not asserted herein of which it may become aware through discovery or other investigation.

**PRAYER FOR RELIEF**

WHEREFORE, Novartis Pharmaceuticals Corporation prays as follows:

That all claims contained in the Government's Complaint against it be dismissed with prejudice.

That it be awarded costs and attorneys' fees.

That it have such other and further relief as this Court deems just and proper.

Dated: September 11, 2014

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